

DEPARTMENT OF HEALTH AND HUMAN SERVICES

JAN 28 1998

Donald L. Emlay
Vice President, Regulatory Affairs
Calgene
1920 Fifth Street
Davis, California 95616

Dear Mr. Emlay

This is in regard to Calgene's consultation with the Food and Drug Administration (FDA) (Center for Veterinary Medicine and Center for Food Safety and Applied Nutrition) on its BXN with Bollgard cotton lines (transformation events 31707, 31803, 31807, 31808, and 42317). According to Calgene, the new cotton varieties have been rendered tolerant to the herbicide Buctril® through expression of the nitrilase gene from *Klebsiella pneumoniae*. They have also been rendered resistant to certain lepidopteran insects through expression of the cryIA(c) gene from *Bacillus thuringiensis* subsp. *kurstaki*.

As part of bringing the consultation regarding these varieties to closure, Calgene submitted a summary safety and nutritional assessment of the genetically modified cotton varieties on September 18, 1997. This communication informed FDA of the steps taken by Calgene to ensure that these products comply with the legal and regulatory requirements that fall within FDA's jurisdiction. Based on the safety and nutritional assessment Calgene has conducted, it is our understanding that Calgene has concluded that the new cotton varieties are not materially different in composition, safety, or any other relevant parameters from cotton lines currently on the market and that they do not raise issues that would require premarket review or approval by FDA. All materials relevant to this notification have been placed in a file designated BNF0047 that will be maintained in the Office of Premarket Approval.

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Based on the information Calgene has presented, we have no further questions concerning these products at this time. However, as you are aware, it is Calgene's continued responsibility to ensure that foods marketed by the firm are safe, wholesome and in compliance with all applicable legal and regulatory requirements.

Sincerely yours,

/s/

Alan M. Rulis, Ph.D.
Director
Office of Premarket Approval
Center for Food Safety and
Applied Nutrition

cc: HFS-200 HFS-205 HFS-206 HFS-226 HFS-235 HFS-246 HFS-247
HFS-13 HFV-200 **BNF0047**